UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/639,207	08/14/00	KAZEMI-ESFARJANI	P 06618-686001

020985
FISH & RICHARDSON, PC
4350 LA JOLLA VILLAGE DRIVE
SUITE 500
SAN DIEGO CA 92122

HM22/1107

EXAMINER	
PAPPU, S	
ART UNIT	**PAPER NUMBER**
1632	5

DATE MAILED: 11/07/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/639,207	KAZEMI-ESFARJANI ET AL.	
	Examiner	Art Unit	
	Sita S Pappu	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-79 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-79 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-25, 26-46 and 50 drawn to a method of screening for genes that modulate polyglutamine toxicity, and the transgenic animal used in the method, classified in class 800, subclasses, 3, 8 and 13.

II. Claims 26-46, 47-49, and 50, drawn to a method for identifying a compound that modulates polyglutamine toxicity in an animal, and the transgenic animal used in the method, classified in class 800, subclass 3, 8 and 13.

III. Claims 51-56, and 64, drawn to a polynucleotide sequence with identity to *Drosophila* TPR2 sequence and a composition comprising a polynucleotide sequence encoding a human TPR2 polypeptide, classified in class 514, subclass 44.

IV. Claims 57-63, drawn to an isolated polynucleotide sequence having identity to a *Drosophila* MLF sequence, and a composition comprising a polynucleotide sequence encoding a human MLF polypeptide, classified in class 514, subclass 44.

V. Claims 65 and 66, drawn to a method of increasing survival of a cell having polyglutamine toxicity, or decreasing apoptosis of a cell, comprising contacting the cell with an amount of TPR2 polypeptide

sequence, classified in classes 424, 514 and 530, subclasses 93.21, 12 and 300, 350 respectively.

VI. Claims 65 and 66, drawn to a method of increasing survival of a cell having polyglutamine toxicity, or decreasing apoptosis of a cell, comprosing contacting the cell with an amount of MLF polypeptide sequence classified in classes 424, 514 and 530, subclasses 93.21, 12 and 300, 350 respectively.

VII. Claims 65 and 66, drawn to a method of increasing survival of a cell having polyglutamine toxicity, or decreasing apoptosis of a cell, comprising contacting the cell with an amount of a polynucleotide sequence TPR2 polypeptide classified in classes 424 and 514, subclasses 93.21 and 44 respectively.

VIII. Claims 65 and 66, drawn to a method of increasing survival of a cell having polyglutamine toxicity, or decreasing apoptosis of a cell, comprising contacting the cell with an amount of a polynucleotide sequence MLF polypeptide, classified in classes 424 and 514, subclasses 93.21 and 44 respectively.

IX. Claims 67-69, 70-71, 72-79, drawn to a method of decreasing polyglutamine toxicity in a cell, or in a tissue or organ of a subject, respectively, having or susceptible to polyglutamine toxicity , comprising contacting the cell, tissue or organ with an amount of J domain containing TPR2 polypeptide, and to a method of decreasing the severity of a

frontotemporal dementia, prion disease, polyglutamine disorder or protein aggregation disorder in a subject having or at risk of a frontotemporal dementia, prion disease, polyglutamine disorder or protein aggregation disorder, comprising administering to the subject an amount of J domain containing TPR2 polypeptide sequenceclassified in class 424, subclass 93.21.

X. Claims 67-69, 70-71, 72-79, drawn to a method of decreasing polyglutamine toxicity in a cell, or in a tissue or organ of a subject, respectively, having or susceptible to polyglutamine toxicity , comprising contacting the cell, tissue or organ with an amount of J domain containing MLF polypeptide, and to a method of decreasing the severity of a frontotemporal dementia, prion disease, polyglutamine disorder or protein aggregation disorder in a subject having or at risk of a frontotemporal dementia, prion disease, polyglutamine disorder or protein aggregation disorder, comprising administering to the subject an amount of J domain containing MLF polypeptide sequenceclassified in class 424, subclass 93.21.

XI. Claims 67-69, 70-71, 72-79, drawn to a method of decreasing polyglutamine toxicity in a cell, or in a tissue or organ of a subject, respectively, having or susceptible to polyglutamine toxicity , comprising contacting the cell, tissue or organ with an amount of a polynucleotide sequence encoding the J domain containing TPR2 polypeptide, and to a

method of decreasing the severity of a frontotemporal dementia, prion disease, polyglutamine disorder or protein aggregation disorder in a subject having or at risk of a frontotemporal dementia, prion disease, polyglutamine disorder or protein aggregation disorder, comprising administering to the subject an amount of a polynucleotide sequence encoding the J domain containing TPR2 polypeptide, classified in class 424, subclass 93.21.

XII. Claims 67-69, 70-71, 72-79, drawn to a method of decreasing polyglutamine toxicity in a cell, or in a tissue or organ of a subject, respectively, having or susceptible to polyglutamine toxicity , comprising contacting the cell, tissue or organ with an amount of a polynucleotide sequence encoding the J domain containing MLF polypeptide, and to a method of decreasing the severity of a frontotemporal dementia, prion disease, polyglutamine disorder or protein aggregation disorder in a subject having or at risk of a frontotemporal dementia, prion disease, polyglutamine disorder or protein aggregation disorder, comprising administering to the subject an amount of a polynucleotide sequence encoding the J domain containing MLF polypeptide, classified in class 424, subclass 93.21.

Claims 26-46 and 50 embrace the Inventions of Groups I and II. Should either of the Inventions I or II be elected, the claims 26-46 and 50 will be examined to the extent they encompass the subject matter elected.

Claims 65 and 66 embrace the Inventions of Groups V, VI, VII and VIII. Should one of the groups V, VI, VII, or VIII be elected, claims 65 and 66 will be examined to the extent they encompass the subject matter elected.

Claims 67-79 embrace the Inventions of Groups IX, X, XI and XII. Should one of the groups IX, X, XI, or XII be elected, claims 67-79 will be examined to the extent they encompass the subject matter elected.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are distinct from each other. Invention I is directed to a method of screening for genes that modulate polyglutamine toxicity using a transgenic animal and Invention II is directed to a method of identifying a compound that modulates polyglutamine toxicity using a transgenic animal. These methods require independent and materially different protocols. The methods of Invention I are not required for Invention II and vice versa.

Inventions III and IV are directed to different polynucleotide sequences (TPR2 and MLF) and their compositions and do not require the transgenic animal or the methods of Inventions I and II.

Inventions V-VIII are directed to *in vivo* methods of using the TPR2 and MLF polypeptide and their corresponding polynucleotide sequences in increasing the survival or decreasing the apoptosis of a cell and do not require the transgenic animal or the methods of Inventions I-IV. Further, Inventions V-VIII are directed to different polynucleotide sequences and their peptide products for *in vivo* use and are, thus, distinct from one another. Further, peptides and nucleic acids are substantially different in terms of structural, chemical, physical and biological properties, are made using substantially different techniques and can be used for substantially different purposes. It is particularly noted that the nucleic acid is not required for the production of the peptide as peptides can be synthesized or purified from cells.

Inventions IX-XII are directed to *in vivo* methods of reducing polyglutamine toxicity in a cell, tissue or organ of a subject and require independent methods distinct from Inventions I-VIII. Further, Inventions IX-XII are directed to different polynucleotide sequences and their peptide products for *in vivo* use and are, thus, distinct from one another. Further, similar to the Inventions V-VIII, nucleic acids and peptides are distinct from each other.

Inventions XIII-XVI are directed to methods of therapy for treating various disorders and are materially different from the methods of the Inventions I-XII. Further, Inventions XIII-XVI are directed to different

polynucleotide sequences and their peptide products for therapeutic use and are, thus, distinct from one another. Further, similar to the Inventions V-VIII, nucleic acids and peptides are distinct from each other.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sita S Pappu whose telephone number is (703) 305-5039. The examiner can normally be reached on Mon-Fri (9:00 AM - 5:00 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Karen Hauda can be reached at (703) 305-6608. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-2758.

Anne-Marie Baker

ANNE-MARIE BAKER
PATENT EXAMINER

S. Pappu
October 31, 2001